Better treatments...
Better lives.

Return of medically significant research findings

SOP ID NUMBER: EDP

VERSION 1.0

1.0 CONTENTS

2.0 DOCUMENT HISTORY

Version	Date	SOP developed by and date	SOP approved by and date	Approval signature	Next review
1.0	01/09/2017	BBC Naomi Sprigg 01/09/2017	CEO Delaine Smith		01/09/2020

3.0 ABBREVIATIONS

ALLG	Australasian Leukaemia and Lymphoma Group
ALLG Office	ALLG Business and Central Trial Office
BBC	Biobank Coordinator
CEO	Chief Executive Officer
CI	Chief Investigator of trial
EDP	Ethically Defensible Plan
HREC	Human Research Ethics Committee
IIT	Investigator Initiated Trial
LSC	Laboratory Science Committee
NHMRC	National Health and Medical Research Council
NOK	Next Of Kin
PI	Principal Investigator (the local hospital/site clinician investigator)
PICF	Participant Information and Consent Form
SAC	Scientific Advisory Committee
SOP	Standard Operating Procedure

4.0 PURPOSE

The ALLG is a not-for-profit clinical trial organisation that Sponsors local Investigator Initiated clinical trials. ALLG has a Board of Directors made up of clinicians and non-clinicians, and a Scientific Advisory Committee which oversees the conduct of clinical trials. The ALLG plans, designs, conducts, monitors and publishes IIT's.

Pivotal to the successful conduct of trial-associated translational research is collection of blood and tissue samples used for compelling ethical research that will lead to discoveries and contribute to future cancer cures.

The ALLG facilitates the collection of biospecimens for research by either

a. Consent to ALLG clinical trial participation, in which the use of the biospecimens is defined within the ethically approved research trial, or
b. Consent to participation in the National Blood Cancer Registry, and the option to donate samples to the ALLG biobank, in which the use of biospecimens is for future unspecified ethically approved research.

Donors are informed at the time of and during the process of consent that their sample may be used in genetic research and that research findings may be made that could be of significance to them or their family. If meaningful information has been obtained from the research that may have implications to their overall health care management, or that of their family, the ALLG, CI, PI and treating clinician will attempt to contact them.

The ALLG EDP SOP has been developed in accordance with the requirements of the NHMRC National Statement (2007) on the Ethical Conduct of Human Research.

> Section 3.5.1 states: *"Where research may discover or generate information of potential importance to the future health of participants or their blood relatives, researchers must prepare and follow an ethically defensible plan to disclose or withhold that information."*
>
> Section 3.5.2 states: *"This plan must take into account the clinical relevance of the research information, the types of genetic test used in research, and the results of those tests."*

5.0 RESPONSIBILITIES

Where a finding relevant to a donor has been returned by a researcher, the ALLG, CI, HREC, PI and treating clinical team are responsible for the implementation of this SOP.

6.0 ALLG BIOBANK POLICY

6.1 Researchers are required to report significant medical research findings to both their Research Institution's HREC and to the ALLG Office.

6.2 The researcher should repeat the test if left over sample material is available in order to confirm their finding before submitting the report.

6.3 In the event that the HREC responsible for the approval of the research does not have a procedure for reporting of incidental findings then the ALLG EDP SOP is to be followed for the purpose of reporting the incidental finding.

6.4 In the event that a donor is found to have previously indicated on their PICF that he/she did not wish to be contacted about medical research findings then the ALLG recommends following the NMHRC 'National Statement on Ethical Conduct in Human Research' 2007, guideline, which states:

> *3.5.1C Where participants or relatives prefer not to receive genetic information that is important for their health, they should be advised that they will be approached to confirm this decision when the results of the research are available.*

Note: At no time should the Donor be identified to the HREC.

7.0 NOTIFICATION OF FINDING

All incidental findings must be reported, the following outlines how the notification is to occur.

7.1 The ALLG Office is notified of potentially important medical information from:

- The researcher and/or
- The HREC of the research institution where the research is being undertaken.

7.2 The ALLG BBC will establish the identity of the donor and procurement site, and;

- Identifying donor information
- A copy of the signed PICF
- An inventory of samples in storage.
- Details regarding whether or not the donor wished to be contacted.

7.3 The ALLG will notify the CI of the trial and the PI at the research institution where the participant consented and sample was donated. ALLG will provide details of

- Identifying donor information
- The research findings
- Details if the donor wished to be contacted.

7.4 The PI will notify the treating clinician.

8.0 DELIBERATION OF FINDING

8.1 The treating clinician, relevant clinical team, and site PI will deliberate regarding the donor notification process. In the event that the donor is deceased then consideration is to be given to the notification of NOK. *May seek guidance from the HREC.

8.2 The site PI will inform the responsible HREC of the research project and notify the ALLG Office of the decision.

8.3 If determined that the donor (or NOK in the case of deceased donor) is not be contacted then no further action is required.

9.0 CONTACTING THE DONOR

9.1 If it has been determined the donor should be notified, the treating clinician will contact the donor (or NOK in case of deceased donor) by phone and/or in writing. If contact is in writing the letter should indicate that an "incidental finding was made during the course of research that utilised their donated tissue and that this finding could have medical implications for them or their family".

9.2 The treating clinician will consider the wishes of the donor at time of consent regarding the return of medically significant research findings when contacting the donor.

9.3 If the treating clinician is unable to establish contact with the donor then consideration to contacting the NOK will be given.

10.0 RELEASE OF INFORMATION

10.1 The treating clinician will arrange a consultation for discussion of research findings.

10.2 Treating clinician may then refer to other specialist consultants if appropriate (e.g. familial cancer clinic, genetic counsellor, etc.). Referral complete.

10.3 Treating clinician is to report the final outcome to responsible HREC of the project and ALLG Office.

11.0 RETURN OF MEDICALLY SIGNFIGANT RESEARCH FINDINGS DIAGRAM

Figure 1 Reporting and notification process